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EXAMINER

HOBBS, MICHAEL L

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4151

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

2. Claims 33 and 35 are objected to because of the following informalities: on line 2 of claims 34 and 35, applicant refers to "container is conductive via" which the examiner's assumption is that the applicant meant conducted instead of conductive. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The phrase "box-type" in claim 21 is a relative term which renders the claim indefinite. The term "box-type" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the

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art would not be reasonably apprised of the scope of the invention. Furthermore, this term renders the shape of the culture apparatus indefinite since it is unclear what specific shape the culture apparatus is supposed to take, i.e. cube, rectangle. See MPEP § 2173.05 (b).

6. Appropriate corrective action is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21, 25, 26, 27, 28, 29, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Burkovich et al. (U.S. 5,232,665).

9. Burkovich teaches a multi-linear automatic apparatus for real-time analysis of immunoassays contained within process carriers. For claim 21, Burkovich teaches a plurality of process carriers (Abstract) used to carry samples that are translated to an inlet chamber for processing (col. 4 lines 14-16). Also, Burkovich includes an incubator within the processing chamber (col. 7 lines 11-12, Fig. 1 element 19) and processing positions for removing and replacing liquids into the reaction vessels (col. 4 lines 35-37). Furthermore, Burkovich includes a translating means for moving the reaction vessels from station to station (col. 4 lines 25-26) with electronics and software that control the

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process (col. 6 lines 49-50). With regard to the limitation of claim 21 that the processing chamber is aseptic, it is noted that the teachings of Burkovich requires that the processing chamber has a sterile environment.

10. For claim 25, Burkovich further teaches that a plurality of reaction vessels are used (Abstract) **(divided into plural number of spaces by a separator)** which are translated to the processing chamber by a translating means (col. 4 lines 25-26) **(practicable separator door)**. Also, for claim 26 Burkovich teaches a washing station within the processing chamber where the reaction vessel is washed after being incubated (col. 7 lines 12-13, Fig. 1 element 26). Regarding claim 27, Burkovich teaches a pump that supplies fluid from the re-suspension buffer supply to the reaction vessel (col. 11 lines 23-25). For claim 28, Burkovich teaches that the sample carriers are transferred to an instrument for reading the results of the reaction within the processing chamber (col. 11 lines 5-7). Also, for claim 29, the removal of the tag within the sample container happens at the wash station where the tag is removed by aspiration (col. 2 lines 42-43 & 46-47). For claim 33, Burkovich teaches that the culture vessels can be used only once, i.e. disposable. For claim 34, Burkovich teaches that the liquids are processed using a syringe type pump (col. 11 lines 18-19). Therefore, Burkovich teaches the limitations of claims 21, 25, 26, 27, 28, 29, 33 and 34.

11. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Bisconte (U.S. 4,800,164).

12. Bisconte teaches an automatic device for the analysis and cloning of cellular structures that includes a circular transparent plate containing micro-wells disposed in

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circular concentric rows with a microscopic device used for optical testing of the micro-wells (Abstract). Furthermore, for claim 36 the microscope allows the optical analysis of the density, form of and associations of the cells (col. 2 lines 5-6). Also, applicant defines "non-invasion measurement" to be cell measurements characterized by "non-contact, non-broken" and is being interpreted here to include any cell measurement test that does not damage the cells, i.e. measuring cell density. In light of this interpretation, optical testing such as that performed by a microscope is a "non-invasive measurement". Furthermore, "static adhesion" is being interpreted to mean a cell culture with no dynamic conditions such as convective currents or media flow across the chamber. Therefore, Bisconte meets the limitations of claim 36.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burkovich et al. (U.S. 5,232,665) in view of Creed et al. (U.S. 4,666,722).

17. For claims 22 and 23, Burkovich remains silent regarding introducing a sterile gas to the portions of the box or that the sterile gas is ozone.

18. Creed discloses a sterile cooling method that is used in the packaging of food products and fluids. For claim 22, Creed discloses that cars containing package-laden trays are sent to an unloading station where the trays are removed by the clamping and transfer device (col. 3 lines 2-5). Furthermore, the cars are sent to the sterilizing apparatus and after the doors to the apparatus are closed and locked, the device is sterilized by superheated steam and pressurized by sterile air (col. 5 lines 10-14). Also, for claim 23 the air used by Creed in the sterilization process can be a mixture of air and ozone (col. 5 lines 14-15). Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to employ the sterilization apparatus as

suggested by Creed within the teachings of Burkovich in order to sterilize the trays. The suggestion for doing so at the time would have been in order to sterilize the package-laden trays and cool the trays in a sterile environment (col. 1 lines 4-6).

19. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burkovich et al. (U.S. 5,232,665) in view of Takagi et al. (JP2001-238663).

20. Burkovich teaches a CPU that controls the separate stations that run an assay on each reaction vessel, but remains silent regarding the interior pressure of the stations. Takagi teaches a method for culturing cells and tissues that minimizes contamination through a controlled environment. For claim 24, Takagi teaches the pressure within the autoclave at a pressure of 2 atmospheres while sterilizing the culture device (page 2 [0005] lines 4-6 of machine translation). At the time of the invention, it would have been obvious to one of ordinary skill in the art to employ the pressurized autoclave as suggested by Takagi within the teachings of Burkovich in order to have the pressure within the autoclave to be higher than the external pressure. The suggestion for doing so at the time would have been in order to prevent contamination of the culture after disassembling the culture device (page 2 [005] lines 3-4 of machine translation).

21. Claims 30, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burkovich et al. (U.S. 5,232,665) in view of Matsuda et al. (U.S. 4,966,853).

22. Burkovich remains silent regarding claim 30 where the peeling or recovering unit is a vibration unit or a rotation unit and for the press unit used for changing environmental conditions for claim 31. Also, for claim 32, Burkovich does not teach a

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press unit that is operated by mechanical pressing. Burkovich does teach that electronics and software are used to control the process (col. 6 lines 49-50) and that a translating means is used to move the reaction vessels from one station to another (col. 4 lines 25-26).

23. Matsuda teaches a cell culturing apparatus that includes a loop with a plurality of culturing racks connected in a series. Regarding claim 30, Matsuda teaches a culture vessel that is a roller bottle type of culture vessel (col. 4 lines 23-24). Typically, roller bottles are used where the culture contained within the bottle needs to be agitated to allow an air exchange between the growth substrate and the air contained within the bottle. It would be obvious to one of ordinary skill in the art to modify the culturing apparatus of Burkovich based on the suggestion by Matsuda to agitate or "peel" the substrate from the culture vessel.

24. For claim 31, Matsuda teaches a cap removing station for the roller bottles that is contained within a sterilized chamber (col. 17 lines 46-50). By closing the roller bottle with a cap, the culture within the bottle can be sealed at a pressure greater than the surrounding pressure or the waste gases due to the culturing process can be retained in the bottle which would adjust the "environmental conditions" within the bottle.

Regarding claim 32, Matsuda teaches a cap fitting station that the roller bottles proceed to after being filled with a liquid medium (col. 19 lines 24-27) where the bottles then proceed to the next station. Matsuda does not disclose that the cap fitting unit is operated by a magnet or by mechanical pressing, but Matsuda does disclose that the caps are capped by a cap fitting unit (col. 19 lines 36-37, Fig. 39 element 827) and one

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of ordinary skill in the art would know that “capped” includes mechanical means of attaching a cap such as **mechanical pressing**. Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to employ the cap fitting unit as suggested by Matsuda within the teachings of Burkovich to cap the roller bottles after filling with liquid medium. The suggestion for doing so at the time would have been limit contamination of the culture during movement between each station.

25. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burkovich et al. (U.S. 5,232,665) in view of Sawamura et al. (U.S. 4,090,921).

26. Burkovich remains silent regarding a sterilized tube connected to the container for supplying a liquid culture, washing liquid or a chemical. Sawamura teaches an automatic cultivating apparatus used for the cultivation of tissues or cells with the ability to maintain a pre-determined atmosphere via atmospheric controls. Furthermore, the tissues or cells are inserted into a plurality of empty cultivating containers which will be filled with nutrient solution (col. 4 lines 57-59). Also, the nutrient solution is contained within a trough which is connected to a tube which is further connected to a discharge nozzle (col. 4 lines 5-7, Fig. 3 elements 24, 24d & 25). Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to employ the tube and discharge nozzle as suggested by Sawamura within the teachings of Burkovich in order to dispense a nutrient solution to the culturing vessel. The suggestion for doing so at the time would have been in order to meter the preferred amount of solution to the dish.

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27. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bisconte (U.S. 4,800,164) in view of Mishima et al. (U.S. 5,182,193).

28. Bisconte does not teach the limitation where the measurement device is equipped with electrodes and the culture is placed in between. Mishima teaches a method for measuring biomass within a bioreactor that includes measuring the electrical capacitance across a pair of electrodes attached to the bioreactor. Furthermore, the cells may or may not be immobilized within the bioreactor (Abstract) and the electrical capacitance is measured across the bioreactor (Fig. 1 element 5). Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to employ the electrodes as suggested by Mishima within the teachings of Bisconte in order to measure the electrical capacitance across the bioreactor. The suggestion for doing so at the time would have been in order to measure the on-line quantities of micro-organisms without having to take samples from the tank (Abstract).

29. Claims 38 and 39 rejected under 35 U.S.C. 103(a) as being unpatentable over Bisconte (U.S. 4,800,164) in view of Bylina et al. (U.S. 5,914,245).

30. Bisconte does not teach the limitations of claims 38 and 39.

31. Bylina teaches a solid phase enzyme kinetics screener in micro-colonies that permits high-throughput screening of enzyme libraries by time course analysis of single-pixels using adsorption, fluorescence or FRET (fluorescence resonance energy transfer) for detecting optically distinct regions composed of micro-colonies of cells. For claim 38, the tester directs monochromatic light from above the target in order to obtain kinetic and spectral data from the micro-colonies (col. 2 lines 32-33 & col. 5 lines 30-

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32). Furthermore, for claim 39 the tester of Bylina analyzes the micro-colonies through either fluorescence (**fluorometry**) or FRET (Abstract) based on the emission from either a donor or acceptor moiety (col. 11 lines 15-17). Therefore, it would have been obvious to one of ordinary skill in the art to employ the enzyme kinetic screener of Bylina within the teachings of Bisconte in order to test the cell density of the micro-colonies. The suggestion for doing so at the time would have been in order to increase the throughput of testing and decrease the assay volume (col. 2 lines 5-8).

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The art taught by Barbera-Guillem (U.S. 6,673,595) discloses an automated cell management system that includes an incubator and a centrifuge.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL L. HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mikhail Kornakov can be reached on (571) 272-1303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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MLH

/Michael Kornakov/
Supervisory Patent Examiner, Art Unit 4151